



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2004-0144; FRL-9346-9]

RIN 2070-ZA16

1-Naphthaleneacetic acid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of 1-naphthaleneacetic acid, potassium and sodium salts in or on potatoes. Stehekin, LLC petitioned EPA for clearance of use of this pesticide under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2004-0144. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only

in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703)-305-5611; email address: kearns.rosemary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification

System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2004-0144 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any

CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2004-0144, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54629) (FRL-8843-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a (d)(3), announcing the filing of a pesticide petition (PP 0F7687) by Stehekin, LLC, 1012 Good Lander Drive, Selah, Washington 98942. The petition requested that a tolerance exemption be established for residues of the fungicide 1-naphthaleneacetic acid (1-naphthaleneacetamide), on potatoes. That notice referenced a summary of the petition prepared by Stehekin, LLC, the registrant, which is available in the docket,

<http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon a revised petition which requested a tolerance and review of the data supporting the petition, EPA has determined that it is appropriate to establish a tolerance in association with the use of 1-naphthaleneacetic acid (1-naphthaleneacetamide) on potatoes.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 1-naphthaleneacetic acid, its salts, ester, and acetamide which are collectively referred to as naphthalene acetates

(NAA) including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with NAA follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Based on structural activity relationship and metabolism data, all forms of 1-naphthaleneacetic acid, its salts, ester, and acetamide are expected to exhibit similar toxicological effects. Therefore the Agency concluded that required toxicity testing on any form should serve for all members of this group of chemicals.

Naphthalene acetates have low acute toxicity via the oral, inhalation and dermal routes of exposure. 1-Naphthaleneacetic acid is not a skin irritant or a dermal sensitizer. The 1-naphthaleneacetic acid and its sodium salt were found to be irritating to the eye. Repeated exposure oral toxicity studies in rats and dogs resulted in decreased body weights and body weight gains accompanied by decreased food consumption.

The major target organs of subchronic and chronic oral exposure were the liver, stomach and lung. Repeated oral exposure also resulted in decreased hematocrit and hemoglobin along with reduced RBC count in rats and dogs and hypocellularity of the bone marrow in dogs.

There was no developmental toxicity at the highest dose of 1-naphthaleneacetic acid tested in the rat or in the rabbit, but developmental toxicity (decreased fetal weight

and minor skeletal changes) were seen in rats orally gavaged with the sodium salt.

Reproductive effects of naphthaleneacetic acid sodium salt were limited to reduced litter survival and pup weight throughout lactation in both generations of offspring in a 2-generation reproduction study.

Naphthaleneacetic acid and its acetamide and the ethyl ester were tested for mutagenic effects in a gene mutation bacterial assay, mouse lymphoma assay, and mouse erythrocyte micronucleus assay, mouse lymphoma assay, and mouse erythrocyte micronucleus assay and were not mutagenic. Additionally 1-naphthaleneacetic acid was tested for mitotic gene conversion and dominant lethality in rats and found to be negative.

Carcinogenicity studies of NAA in mice and in rats for the 1-naphthaleneacetic acid group showed no evidence of carcinogenicity. Specific information on the studies received and the nature of the adverse effects caused by NAA as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document “Naphthalene Acetates HED Risk Assessment for Section 3 Proposed New Use on Potato Seed Pieces” at pages 10 through 14 in docket ID number EPA-HQ-OPP-2004-0144.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which

no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for 1-naphthaleneacetic acid used for human risk assessment is shown in Table 1 of this unit.

Table 1.—Summary of Toxicological Doses and Endpoints for 1-Naphthaleneacetic acid for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	An acute RfD for the general population subgroups was not selected because no effect attributable to a single (or few) day(s) oral exposure was observed in animal studies.		
Chronic dietary (All populations)	NOAEL= 15 mg/kg/day UF _A = 10x UF _H = 10x	Chronic RfD = 0.15 mg/kg/day cPAD = 0.15 mg/kg/day	Chronic Toxicity –Dog LOAEL = 75 mg/kg/day based on stomach lesions in 75% of the males and by slight sinusoidal histocytosis in the liver of 50% of the males
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 300 mg/kg/day UF _A = 10x UF _H = 10x	LOC for MOE = 100	Dermal Toxicity Study-Rat LOAEL = 1000 mg/kg/day based on reduced body weight gain and food efficiency
Dermal intermediate-term (1 to 6 months)	Dermal (or oral) study NOAEL= 300 mg/kg/day UF _A = 10x UF _H = 10x	LOC for MOE = 100	Dermal Toxicity Study - Rat LOAEL = 1000 mg/kg/day based on reduced body weight gain and food efficiency
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x	LOC for MOE = 100	Developmental Toxicity Study-Rat LOAEL = 250 mg/kg/day based on decreased body weight gain during the gestation period
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL = 25 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x	LOC for MOE = 100	Subchronic Study-Dog LOAEL = for systemic toxicity=150 mg/kg/day based on lesions of the GI tract and hypocellularity of the bone marrow

Cancer (all routes)	A “not likely” human carcinogen.		

LOAEL = lowest observed adverse effect level.

LOC = level of concern.

MOE = margin of exposure.

N/A = not applicable.

NOAEL = no observed adverse effect level.

PAD = population adjusted dose (a = acute, c = chronic).

POD = Point of Departure = A data or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures.

RfD = reference dose.

UF = uncertainty factor.

UF_A = extrapolation from animal to human (interspecies).

UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to NAA, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances in 40 CFR 180.155. EPA assessed dietary exposures from NAA in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for NAA; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance level residues for all registered uses, 100% crop treated for all commodities with existing tolerances, and default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that NAA does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for 1-naphthaleneacetic. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for NAA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of 1-naphthaleneacetic acid. Further, information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, estimated drinking water concentrations (EDWCs) of naphthaleneacetic acetates for peak and average concentrations of naphthalene acetates in surface water are 0.02 ppm and 0.003 ppm respectively. The modeled peak and average EDWCs for ground water is 0.00002 ppm.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value .003 ppm was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There is a potential for short-term residential exposure to NAA from ornamental uses.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found naphthalene acetates to share a common mechanism of toxicity with any other substances, and NAA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NAA does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA

either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is low concern (and no residual uncertainty) for prenatal and/or postnatal toxicity resulting from exposure to the NAA group of chemicals. The available data provided no indication of increased susceptibility (quantitative or qualitative) to rats or rabbits to *in utero* exposure to naphthalene acetates or to prenatal and postnatal exposure in rat reproduction studies,

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. Acceptable developmental toxicity studies in the rat and rabbit, and an acceptable reproduction study in the rat are available. Recent changes to 40 CFR part 158 require acute and subchronic neurotoxicity and immunotoxicity studies. An immunotoxicity study is not available. However, the toxicology data base for NAA does not show any evidence of treatment-related effects on the immune system and the overall weight of evidence suggests that this chemical does not directly target the immune system. Consequently, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment, and therefore, an additional safety factor is not needed to account for lack of this study. The toxicity database does not show any indications of neurotoxicity or neuropathology (the liver, stomach, lung, and hematological parameters are the target organs based on repeat toxicity studies in rats, mice and dogs).

ii. There is no indication that NAA is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that NAA, results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in dietary assessment and in the ground and surface water modeling used to assess exposure to NAA in drinking water. EPA made conservative (protective) assumptions in the residential handler assessment. Post-application exposure to residents is not expected.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, NAA is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to NAA, from food and

water will utilize 2% of the cPAD for children 1-2 years old the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There is potential for short-term residential exposure to NAA from ornamental uses. Oral, dermal and inhalation exposures cannot be combined for short-term aggregate risk assessment, however, because oral exposure endpoints are not based on common toxicological effects with either dermal or inhalation endpoints. Estimated dermal and inhalation MOEs for residential exposure to naphthalene acetates are 3,800 and 58,000 respectively. These estimated exposures are greater than the target MOE of 100 and therefore not of concern. Although a POD from an oral study was used to assess residential handler inhalation risks for NAA, the Agency does not believe this assessment is under-protective of adult handlers. Inhalation MOEs calculated for residential handlers were all >58,000, thus providing an ample margin of safety to account for any uncertainties in route-to-route extrapolation.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Intermediate-term exposure to NAA is not expected based on residential use patterns. Therefore, NAA is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, NAA, is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to NAA residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (HPLC methods (Method NAA-AM 001 and Method NAA-AM-002) for determination of NAA in plant commodities have been submitted and reviewed. These methods have been subjected to successful independent laboratory validations. Acceptable recoveries were obtained from apples, olives and olive oil fortified with NAA at the method limit of quantitation (LOQ; 0.01 ppm) and at 1.0 ppm.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture

Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for residues of naphthalene acetates. Therefore, there are no trade issues with this action.

C. Revisions to Petitioned-For Tolerances

The applicant's petition requested an exemption from the requirement of a tolerance for this seed potato application but upon review of submitted information, the Agency determined that a potato tolerance is needed. In lieu of providing field trial data, a theoretical calculation was provided, to show that residues of 1-naphthaleneacetic acid on potatoes will be less than the analytical method's level of quantitation (0.01 ppm) when using the label application rates on potato seed pieces. The Agency determined that a tolerance at the level of quantitation is appropriate and that an exemption is not appropriate because some residues below the level of quantitation may be present and there is toxicological concern for NAA.

V. Conclusion

Therefore, tolerances are established for residues of 1-naphthaleneacetic acid and its conjugates calculated as 1-naphthaleneacetic acid from the application of 1-naphthaleneacetic acid, its ammonium, sodium, or potassium salts, ethyl ester, and acetamide in or on food commodities as follows: in or on potato at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 27, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.155 is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.155 1-Naphthaleneacetic acid; tolerances for residues.

(a) * * *

Commodity			Parts per million		
Potato	*	*	*	*	*
	*	*	*	*	0.01

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